PATENT
Attorney Docket No. 10618.0004

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	
Alain Rambach *et al.*	Group Art Unit: 1657
Application No.: 10/528,824	Examiner: Herbert J. Lilling
Filed: March 23, 2005	
For: Method of Detecting Methicillin-Resistant Microorganisms (as amended)	Confirmation No.: 6976

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

PETITION UNDER 37 C.F.R. §§ 1.144 and 1.181
FOR WITHDRAWAL OF RESTRICTION REQUIREMENT

Pursuant to 37 C.F.R. § 1.144 and 37 C.F.R. § 1.181, Applicants respectfully petition seeking review of the restriction requirement set forth in the Office action mailed February 21, 2008. The restriction requirement was made final in the Office action mailed June 13, 2008. Applicants respectfully request withdrawal of the restriction requirement for two separate reasons. First, there is unity of invention between the restricted claims because all of the claims encompass a common special technical feature. Second, the reliance on an alleged "serious search and examination burden" is misplaced as that is not a basis for restriction under 37 C.F.R. § 1.475. Moreover, even if it were pertinent, there is no undue burden on the examiner to search and examine the subject matter of all of the claims because that subject has already been searched

and fully examined in three Office actions that precede the restriction requirement. Finally, if the restriction requirement is maintained, Applicants request that the Office remove ambiguity existing in the written record in view of comments made in the Office action mailed June 13, 2008, by clearly identifying how the claims 17-98 are being restricted.

I. Statement of Facts

This application was filed on March 23, 2005, as a national stage application under 35 U.S.C. § 371 of PCT/US2003/030032, filed on September 26, 2003. With the national stage filing, Applicants filed a Preliminary Amendment. In that Amendment, Applicants amended claims 1-12 and 14, cancelled claim 13, and entered new claims 15 and 16. Claims 1-12, 15, and 16 were directed to a culture medium and claim 14 to method of detecting meticillin-resistant microorganisms using the culture medium.

A first Office action on the merits was mailed July 31, 2006. As the Office indicated "[c]laims 1-12 and 14-16 were examined on their merits." Office action, page 2. Applicants filed an amendment in response on October 25, 2006. Claim 1 was amended to recite the antibiotics that had been recited in dependent claims 4 and 6. Amendment, page 4. As amended, claim 1 recited:

> 1. A culture medium for detecting meticillin-resistant *Staphylococci*, comprising nutrients for the growth of said *Staphylococci*, an antibiotic chosen from the group consisting of cefamandole, cefoxitin, cefmetazole, moxalactam, cefotetan, and flomoxef, and a chromogenic agent that releases a chromophore after hydrolysis with an enzyme that is active in said microorganisms.

Id., page 2. The medium of claim 1 was used in the method if claim 14. *Id.*, page 3.

The Office examined the amended claims and mailed a second non-final Office action on January 29, 2007. All of the pending claims (1, 3, 7, 8, 10-12, and 14-16)

were again examined on the merits. Applicants electronically filed an Amendment on April 30, 2007. A final Office action was mailed July 11, 2007. Thus, at this point during prosecution of the application, claims reciting culture media containing, among other things, cefoxitin, cefmetazole, moxalactam, and flomoxef were fully examined in three Office actions and the pending rejections made final.

Applicants filed a Request for Continued Examination with an Amendment on January 10, 2008. The pending claims were canceled and new claims 17-98 were entered. Claims 17, 37, 52, and 78 are independent. Claim 17 recites:

> 17. (New) A gelled culture medium for detecting methicillin-resistant *Staphylococcus aureus* (MRSA), comprising:
>
> nutrients for the growth of said *Staphylococcus aureus*;
>
> an antibiotic added to the medium before the medium gels, wherein the antibiotic is cefoxitin, cefmetazole, or moxalactam; and
>
> a chromogenic agent that releases a chromophore after hydrolysis with an enzyme that is active in said MRSA.

Amendment, page 3. Claim 37 is essentially identical to claim 17, except that the antibiotic is flomoxef instead of cefoxitin, cefmetazole, or moxalactam. *Id.*, page 5. All four of the antibiotics were recited in the prior claims, and thus were fully examined.

Claims 52 and 78 are method claims. Claim 52 recites:

> 52. (New) A method of detecting the presence or absence of methicillin-resistant *Staphylococcus aureus* (MRSA) in a sample from a patient, comprising:
>
> (a) inoculating a medium comprising (i) nutrients for the growth of said MRSA; (ii) an antibiotic, wherein the antibiotic is cefoxitin, cefmetazole, or moxalactam; and (iii) a chromogenic agent that releases a chromophore after hydrolysis with an enzyme that is active in said MRSA, with said sample;

(b) incubating said medium under conditions that allow growth of said MRSA;

(c) detecting, on said medium, the presence or absence of said MRSA by virtue of the presence or absence of colored colonies.

Id., page 7. Claim 78 is essentially identical to claim 52, except that the antibiotic is flomoxef instead of cefoxitin, cefmetazole, or moxalactam. *Id.*, page 9.

After this Amendment was filed a new Examiner was assigned the application. An Office action was mailed on February 21, 2008, which addressed the new claims. In that paper, the Office objected to composition claims 17-51 under 35 U.S.C. § 132(a) as allegedly containing new matter. Office action mailed February 21, 2008, page 2. The Office stated that "[c]laims 17-51 will not be considered. . . ." *Id.*

That statement was accurate because composition claims 17-51 were not addressed in the restriction requirement included in the February 2008 Office action. The Office asserted that method claims 52-98 fell into two groups. Group I, comprising claims 52-77, was drawn to a first method utilizing a medium comprising, among other things, "an antibiotic, wherein the antibiotic is cefoxitin, cefmetazole, or moxalactam." Group II, comprising claims 78-98, was drawn to a second method utilizing a medium comprising, among other things, "an antibiotic, wherein the antibiotic is flomoxef." *Id.*, page 3. The Office also imposed a multi-component species election requirement. *Id* In addition, the Office stated that claims 52 and 76 are generic.[1] *Id.*, page 7. To summarize, composition claims 17-51 were not subject to either the restriction or the species election requirements as they were not considered. And method claims 52-98

[1] Applicants assume the reference to Group I dependent claim 76 is a typographical error and that reference to Group II independent claim 78 was intended.

were restricted into two groups based on the antibiotics included in the medium used in the methods.

Before responding Applicants had a telephonic interview with the Examiner on March 13, 2008, seeking clarification of the species election requirement. See Interview Summary mailed March 25, 2008. On March 18, 2008, Applicants filed their response to the restriction and species election requirements. Applicants elected Group I, method claims 52-77, with traverse. Response, page 4. Applicants also elected species as required, and identified claims 52-66, 68-72, and 74-77 as encompassing the elected species. *Id.*, page 6. In a footnote, Applicants indicated that "[u]nexamined [composition] claims 17-28, 31-34, and 36 also encompass the elected species." *Id.*

In an Office action mailed June 13, 2008, the Office acknowledged the traverse, but nonetheless made the restriction requirement final. See pages 2 and 3. In characterizing the restriction, however, the Office was inconsistent with the February 2008 Office action, and also with Applicants' March 2008 response. Thus, contrary to the assertions at page 2 of the June 2008 Office action, Applicants had not "elected with traverse Group I, product claims 17-51." The Office had not restricted the claims into a first group of composition claims [17-51] and a second group of method claims [52-98]. Nor had Applicants "elected species which are within the scope of claims 17-28, 31-34, and 36. Instead, Applicants elected species encompassing method claims 52-66, 68-72, and 74-77.

In the June 2008 Office action claims 17-28, 31-34, and 36 were examined on the merits.

II. Argument

A. The Office Should Withdraw the Restriction Requirement

1. There Is Unity of Invention Between Groups I and II

To summarize the restriction requirement, Group I, claims 52-77, is drawn to a method of detecting the presence or absence of methicillin-resistant *Staphylococcus aureus* (MRSA) in a sample from a patient comprising inoculating a medium comprising, among other things, "an antibiotic, wherein the antibiotic is: cefoxitin, cefmetazole, or moxalactam." February 21, 2008, Office action, page 3. Group II, claims 78-98, is drawn to a method of detecting the presence or absence of methicillin-resistant *Staphylococcus aureus* (MRSA) in a sample from a patient comprising inoculating a medium comprising, among other things, "an antibiotic, wherein the antibiotic is: flomoxef." *Id.* According to the Office, "[i]nvention I is patentably distinct from Invention II since the compounds employed are distinct from each other." *Id.* This is the only assertion made by the Office to support its contention that the claims lack unity of invention.

Applicants submit this single assertion is insufficient to establish that restriction is proper in this case. Unity of invention during the U.S. national stage of a PCT application is determined in accordance with 37 C.F.R. § 1.475, with additional guidance provided by M.P.E.P. § 1893.03(d). As this section of the M.P.E.P. explains, "When making a lack of unity of invention requirement, the examiner must (1) list the different groups of claims and (2) explain why each group lacks unity with each other group (i.e., why there is no single general inventive concept) specifically describing the unique special technical feature in each group." "Special technical features" means

"those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art." 37 C.F.R. § 1.475. Where "there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features" the requirement for unity of invention is met. *Id.*

Despite the unsupported assertion to the contrary, there is a special technical feature among the claims of Groups I and II. As explained in the specification in paragraph [0011], the invention "relates to a medium for detecting meticillin-resistant microorganisms, comprising, besides nutrients for the growth of said microorganisms, at least one antibiotic chosen from the group of second or third generation cephalosporins, and a chromogenic agent that releases a chromophore after hydrolysis with an enzyme that is active in said microorganisms." All of the claims in Groups I and II are directed to methods utilizing a culture medium that includes (1) nutrients supporting the growth of methicillin resistant *S. aureus*, (2) an antibiotic which is a second or third generation cephalosporin, and (3) a chromogenic agent that releases a chromophore after hydrolysis by an enzyme produced by the *S. aureus*. Thus, the claims in these two groups fall within this single general inventive concept. The assertion that "[i]nvention I is patentably distinct from Invention II since the compounds employed are distinct from each other" is not only unsupported by any evidence or reasoning, it is incorrect.

Although not dispositive, Applicants note that in the corresponding PCT application the European Patent Office prepared an International Preliminary Examination Report ("IPER") dated April 1, 2004. A copy of the IPER, and the claims of the PCT application, are enclosed as Exhibit 1. Dependent claim 6 recites that the

culture medium includes an antibiotic "chosen from the group consisting of cefoxitin, cefmetazole, moxalactam, cefotetan and flomoxef." The EPO did not determine there was a lack of unity of invention with respect to the recited antibiotics, or with respect to any of the subject claimed in the PCT application. *See* IPER, page second page.

For these reasons, Applicants submit there is unity of invention between claims 55-77 and 78-98. Accordingly, the Office should withdraw the restriction requirement.

2. There Is No Undue Burden Because the Office Has Searched and Examined the Full Scope of the Claims

The Office also contends there would be a serious search and examination burden if restriction is not required, offering four reasons as supporting this contention. February 21, 2008 Office action, page 4. Two of those reasons include (1) an assertion that the inventions have acquired a separate status in the art in view of their different classification with respect to the antibiotic, and (2) the inventions would require a different field of search. *Id.* The Office, however, does not provide any class/subclass information for Groups I and II, rendering these assertions speculative. Moreover, M.P.E.P. § 1850 advises that under PCT Rule 13 an objection for lack of unity of invention should not be raised "merely because the inventions claimed are classified in separate classification groups or merely for the purpose of restricting the international search to certain classification groups."

Moreover, the subject matter of Groups I and II has already been searched. Claim 1, which was substantively examined in three Office actions (see section I above), recited all four of the antibiotics that appear in the claims of Groups I and II. See, for example, Amendment filed April 30, 2007, page 2. With the Amendment filed January 10, 2008, Applicants merely moved the flomoxef embodiments into a separate

group of claims. Thus, the subject matter of Groups I and II has already been searched and the burden postulated by the Office is no burden at all.

The Office also supports the requirement by speculating that "the prior art applicable to one invention would not likely be applicable to another invention," and "the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph." February 21, 2008, Office action, page 4. Yet neither situation came to pass during prosecution of claims directed to both groups of inventions in three Office actions prepared by the previous examiner responsible for this application.

Even if a search or examination burden were relevant to lack of unity under PCT Rule 13, which they are not, there is no such burden here. The Office has already fully searched and examined the subject matter of Groups I and II. Furthermore, the claims of Groups I and II share a special technical feature that provides unity of invention. For all of these reasons, Applicants respectfully request withdrawal of the restriction requirement.

B. Alternative Request for Clarification of the Restriction Requirement

In the event the Office denies Applicants' Petition and maintains the restriction requirement, Applicants alternatively request that the Office remove ambiguities that presently exist in the written record by clearly setting forth the restriction requirement which has been made final. Applicants' understanding of the restriction requirement, is based on the restriction requirement as set forth in the February 2008 Office action. There are, however, statements made in the June 2008 Office action, which Applicants have identified above, which are in conflict with the February 2008 Office action and

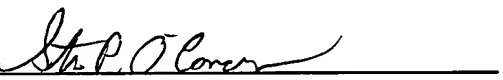
Applicants' March 2008 response. Given the confusion in the written record as to exactly how the Office is restricting the claims, and the potential impact on Applicants rights, for example, rights provided under 35 U.S.C. § 121, Applicants respectfully ask the Office to clearly set forth the restriction requirement and how it applies to claims 17-98 in the event the restriction requirement is not withdrawn.[2]

Please grant any extensions of time required to enter this Petition and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: October 28, 2008

By: 

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[2] Applicants take this opportunity to point out that "a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories: . . . (2) A product and a process of use of said product . . . ." 37 C.F.R. § 1.475. Applicants' pending claims are directed to this combination of categories.